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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,962	09/08/2003	Mendy S. Maccabee	49321-102	3139

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EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
05/22/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/658,962	MACCABEE ET AL.	
	Examiner	Art Unit	
	JENNIFER MYONG M. KIM	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 ,6-8, 21 and 24-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6-8,21 and 24-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed February 24, 2009 have been received and entered into the application.

Response to Arguments

Applicants' arguments filed February 24, 2009 have been fully considered but they are not persuasive. Applicants argue that Biesalski fails to teach, describe, or even suggest treatment of conditions affecting the upper airway (portion of the airway above the vocal cord), of which sinus diseases and sinus wounds are included because all of the disease Biesalski describes are disease of the lower airway (portions of the airway below the vocal cords). Further, Biesalski fails to teach, describe or even suggest a patient population in need of treatment from a sinus disease. This is not found to be persuasive because Biesalski clearly teaches that the preparation is effective for treating functional impairments in the mucous membranes of humans and animals, in particular in the respiratory epithelium and the epithelia of the **nose-throat cavity** which pertains to both nasal and throat cavity. Therefore, this teaching clearly encompasses and over lap instantly claimed loci of "nasal or sinus" mucosa to be treated.

Applicants argue that Belloni also fails to teach the treatment of sinus disease or promotion of sinus wound healing in subjects in need thereof because Belloni describes the use of 13-cis-retinoic acid to treat lung disorders such as chronic obstructive pulmonary disorders, including chronic bronchitis, emphysema and asthma; and thus does not cure the deficiency in Biesalski. This is not found to be persuasive because at the time the invention was made the retinoic acid having wound healing effect was well known in the art in view of Cazares et al. Further, Belloni was cited to show that retinoic acid is available in various topical formulations including depot preparation. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 6-8, 21 and 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biesalski (U.S.Patent No. 5,556,611) of record in view of Cazares et al. (March, 2002) and Belloni (U.S.Patent No. 6,339,107 B1) of record.

Biesalski teaches a pharmaceutical preparation consisting of **retinoic acid** as an active substance suitable for a topical treatment of **mucosal disease** in man and animal. (abstract). Biesalski teaches the preparation can be formulated in an aerosol formulation. (abstract). Biesalski teaches the effective amount of the active substance is from 0.01-50% by weight. (column 6, line 44). This range encompasses and touches Applicants' amounts set forth in claim 8. Biesalski teaches that the preparation is effective for treating **functional impairments in the mucous membranes** of humans and animals, in particular in the respiratory epithelium and the epithelia of the **nose-throat cavity**. Biesalski teaches that the treatment is also useful in **reduced activity of the ciliated epithelium** and disturbances of the mucous membranes of the respiratory tract. (column 10, lines 24-45). Biesalski teaches the preparation is effective for treating acute and chronic bronchitis, acute and chronic functional disturbances due to impairment of tracheobronchial epithelium and bronchopulmonary dysplasia.

Biesalski do not expressly teach the promoting sinus wound healing, non-aerosol, depot formulation of retinoic acid, and the cause of the ciliated epithelial structure damage due to the surgical interventions set forth in claims 7 and 24-27.

Cazares et al. teach that tretinoin (retinoic acid) has **wound healing effect** including cutaneous ulcerations of different causes. (abstract).

Belloni teaches that topical administration of retinoic acid can be formulated as solutions, gels, ointments, creams, suspension, etc. as are well-known in the art. (column 8, lines 14-17). Belloni teaches that retinoic acid can be formulated for oral liquid preparations such as suspensions, elixirs and solutions, as well as **transmucosal**

and **buccal** administration. (column 8, lines 35-40, line 40-65, column 9, lines 1-6). Belloni teaches that retinoic acid can be formulated as a **depot preparation**. (column 10, lines 35-45).

It would have been obvious to one of ordinary skill in the art to employ retinoic acid for the treatment of sinus disease or promoting sinus wound healing because retinoic acid formulation is effective for the treatment of **disorders involving nasal cavity** as taught by Biesalski et al. and because retinoic acid having wound healing effect is well known in view of Cazares et al. One of ordinary skill in the art would readily recognized that upon the administration retinoic acid for the treatment of disorders involving nasal cavity in the patient disclosed by Biesalski et al. would also promote wound healing effect since this known therapeutic effect of retinoic acid would be retained.

It would have been obvious to one of ordinary skill in the art to modify the aerosol formulation of retinoic acid taught by Biesalski to topical non-aerosol, depot formulations such as solution, ointments and transdermal as taught by Belloni for the treatment of damaged ciliated epithelial structure. One would have been motivated to make such a modification because Belloni teaches that retinoic acid can be formulated for the treatment of damaged respiratory walls and because such damaged respiratory walls are routinely treated with depot preparations and various topical formulations. There is a reasonable expectation of success in treating a damaged ciliated epithelium and disturbances of the mucous membrane including increasing ciliated mucosa and mucocilliary density change comprising topical administration of non-aerosol such as

ointment comprising retinoic acid because such formulation and the method of treating damaged or disturbances of the mucus membranes in general as taught by Biesalski.

It would have been obvious to one of ordinary skill in the art to employ retinoic acid preparation taught by Biesalski as modified by Cazares et al. and Belloni for the treatment of any sinus wound healing associated with ciliated epithelium healing or ciliated mucosa including any cause of such damage including the specific sinus surgery set forth in claim 27 because both Biesalski et al. and Belloni teach that the retinoic acid preparation is effective for the treatment of impaired ciliated epithelium and disturbances of the mucous membranes in general and that Cazares et al. teaches the wound healing effect of tretinoin (retinoic acid) was known at the time the invention was made. One would have been motivated to employ the retinoic acid preparation taught by Biesalski as modified by Cazares et al. and Belloni for a condition of damaged ciliated epithelium or a condition of disturbances of the mucous membranes at any cause including the surgical intervention in order to effectively treat the condition and obtain the known wound healing effect of retinoic acid. There is a reasonable expectation of successfully treating damaged ciliated epithelium because both Biesalski and Belloni teach the effectiveness of the preparation in repairing and treating damaged ciliated epithelium or damaged respiratory walls in man or animal with retinoic acid and that retinoic acid having well known would healing effect by Cazares et al.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER M. KIM whose telephone number is (571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer Kim/
Primary Examiner, Art Unit 1617

Jmk
May 15, 2009